20 YEARS ECA Academy Your GMP/GDP Information Source

Pharmacopoeias for Beginners

How to work with the compendia

- Including 3 WORKSHOPS on Interpretation of Monographs (API, DP, Biologic)
- Discuss the use in daily practice!

SPEAKERS:

Dr Raphael Bar
BR Consulting, formerly with Teva, Israel

Dr Françoise Muffat
Sanofi Pasteur, France

Dr Ulrich Reichert
Merck, Germany

Dr Andreas Trute
Roche, Switzerland

6-7 November 2019, Heidelberg, Germany

HIGHLIGHTS:

- About the World Pharmacopoeias (including Chinese and other international Pharmacopoeias)
- General Notices: Legal status, structure, importance
- General Chapters / General Texts/ General Monographs
- Compendial testing / Compendial chromatography / Common Pharmacopoeial Tests
- Structure of USP and Ph. Eur. Monographs
- Workshop: Hands on Interpretation of 3 USP and Ph. Eur. Monographs
- ICH Guidelines and their incorporation into the Ph. Eur.

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager“. Please find details at www.gmp-certification.eu

Pharmacopoeias for Beginners - How to work with the compendia

6-7 November 2019, Heidelberg, Germany

Objectives

When working with the compendia questions that often arise are: When do General Texts apply? What is mandatory / what is flexible? How to implement a compendial procedure? How to handle phamacopoeial reference standards? This Education Course will provide you with support to successfully work with the compendia. The course also includes three interactive workshops and aims at systematically acquainting the participants with:

- The structure and activities of the USP and Ph. Eur. organization bodies, and other international Pharmacopoeias (including Chinese Pharmacopoeia)
- Structure of typical monographs
- General chapters on compendial methodologies
- General approach to compendial testing
- Interpreting all tests listed in a monograph
- Handling pharmacopoeial reference standards
- Implementing a compendial procedure described in a monograph
- Fundamentals of compendial chromatography
- Proper use of analytical balances and weighing
- Qualification of laboratory instruments

Background

US and European pharmacopoeias are independent organizations that set the standards for determining the quality of pharmaceutical products marketed in the US or Europe. These standards govern the quality, strength, purity and potency of active pharmaceutical ingredients, dosage forms and excipients as well as many reagents and solutions used to test these materials.

However, sometimes the pharmacopoeias differ in the quality requirements for the same product or raw material. Compliance, therefore, becomes a major challenge for pharmaceutical companies.

USP–NF standards deemed official by USP are enforceable by the U.S. Food and Drug Administration for medicines manufactured and marketed in the United States and they are recognized and used in more than 130 countries around the globe. The Ph. Eur. is legally binding in 38 European countries and used in over 100 countries worldwide. No wonder then that both pharmacopoeias are widely used by the pharmaceutical industry. Any pharmaceutical testing laboratory must be capable of applying the tests described in the compendial monographs.

In addition, pharmacopoeias are part of the regulations that QPs (Qualified Persons) must comply with for the release of the products as described in the registration dossiers. They also need to manage them in a more and more globalized environment. Therefore, visibility on the on-going drafts and/or work program could be useful for anticipation.

Target Audience

This course is tailored to beginners and newcomers to pharmaceutical analysis in a regulated laboratory as well as experienced personnel who wish to learn about the recent changes introduced in the USP and Ph. Eur. Furthermore, the course is useful for R&D Laboratory data analysts utilizing pharmacopoeial tests, QA involved in reviewing analytical data, and RA personnel who wish to learn about the pharmacopoeial quality standards

Moderator

Dr Raphael Bar

Programme

About the World Pharmacopoeias

- World Pharmacopoeias: Ph. Eur., USP, Chinese Ph., other international Pharmacopoeias
- Structure of Ph. Eur. and Ph. Eur. on line
- Structure of USP and USP on line
- Chinese & other International Pharmacopoeias
- Pharmacopeial Forum, Pharmeuropa
- Harmonization between Pharmacopoeias

General Notices

- Why they are important
- General notices of Ph. Eur., General notices of USP, Alternative procedures, ...

General Chapters / General Texts / General Monographs

- USP
- Ph. Eur.
- What is mandatory?
- What is flexible?
- When is an article of pharmacopoeial quality?

Structure of USP and Ph. Eur. Monographs

- Examples for Monographs
- Technical and style guides
- Knowledge database

WORKSHOPS

Hands on Interpretation of USP and Ph. Eur. monographs of:

- An active substance
- A finished drug product
- A biologic

Balances and analytical weighing

- USP Chapters <41>, <1251>
- Determination of Repeatability and accuracy of balances
- Determination of minimum weight
- From volumetric to gravimetric sample preparation

Introduction into Analytical Instrument Qualification according to Ph. Eur. and USP

- USP General Chapter <1058> Analytical Instrument Qualification
- Type of instruments and risk assessment
- Qualification steps: URS, DQ, IQ, OQ and PQ

Reagents, Solutions & Pharmacopoeial reference standards

- USP and Ph. Eur. requirements for reagents
- Types of solutions (test vs. volumetric solutions)
- Types of reference standards
- USP reference standards
- Ph. Eur. and BP reference standards
- Qualification of secondary reference standard
- Re-use of reference standards?

Compendial Testing Approach

- The four categories of USP tests
- Verification / Validation of compendial procedures
- Singlet testing
- Reportable result
- When is an article of pharmacopoeial quality?

Frequently applied Pharmacopoeial Methods

Pharmacopoeial requirements on tests such as

- Clarity and colour of solution
- pH
- KF titration (validation)
- Frequent wet chemistry tests

Compendial chromatography

- Chapter <621> and Ph. Eur. 2.2.46
- System suitability requirements
- Quantitation of impurities
- Adjustments of method parameters
- Strategies to demonstrate pharmacopoeial compliance

ICH Guidelines and their incorporation into the Ph. Eur., with a focus on the Impurity guidelines

- ICH Q3A on Drug Substance Related Impurities
- ICH Q3B on Drug Product Degradation Products
- ICH Q3C on Residual Solvents
- ICH Q3D on Elemental Impurities
- ICH M7 on potentially mutagenic Impurities

Speakers

Dr Raphael Bar, BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society for Analytical Chemistry. For the lasts ten years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Dr Françoise Muffat, Sanofi Pasteur, France

Françoise Muffat is a pharmacist who has more than 25 years experience in pharmaceutical industry. She had various positions in Quality, Regulatory Affairs and Pharmaceutical Affairs at Merial (veterinary medicines), Rhône-Poulenc Rorer, Aventis, Sanofi Winthrop Industrie, France (human medicines). She is presently in charge of Pharmacopoeia & Quality Intelligence at Sanofi Pasteur, Lyon, France.

Dr Ulrich Reichert (M.D.R.A.), Merck, Germany

Dr Reichert is Head of Pharma and Food Materials in the Regulatory Management organization of Merck Life Science. He is, amongst other things, responsible for the preparation of regulatory dossiers for pharmaceutical starting materials (Master Files). He is experienced in regulatory requirements and analytical methods for pharmaceutical raw materials and member of Ph. Eur. expert groups at the EDQM.

Dr Andreas Trute, Roche, Switzerland

Dr Trute is a pharmacist and received his Ph.D. in pharmaceutical biology from the University of Münster, Germany. He worked in several QA positions at Novartis Pharma AG, Switzerland (for solid formulations) and Roche Diagnostics GmbH, Penzberg, Germany (for biotech APIs). Since 2014, Dr Trute is working for F. Hoffmann-La Roche, Basel, Switzerland. He is deputy Responsible Person (Switzerland) for Investigational Medicinal Products (IMPs).

Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. It takes only about 45 minutes to get from Frankfurt to Heidelberg.
TLS - http://www.tls-heidelberg.de
Lufthansa Bus - http://www.transcontinental-group.com/en/frankfurt-airport-shuttles
PMJ - http://www.pmj-fahrservice.de
Train - You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. http://www.bahn.de

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Pharmacopoeias for Beginners - How to work with the compendia
6-7 November 2019, Heidelberg, Germany
☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No, if applicable

Street/P.O. Box

City Zip Code Country

Phone/Fax E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancelation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Wednesday, 6 November 2019, 09:00 h – 17:45 h
(Registration and coffee from 08:30 h – 09:00 h)
Thursday, 7 November 2019, 08:00 h – approx. 16:15 h

Venue

Heidelberg Marriott Hotel
Vangerowstrasse 16
69115 Heidelberg, Germany
Phone +49 (0)6221 – 908 0
Info.heidelberg@marriott.com

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.
VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the event.
Reservation should be made directly with the hotel.
Early reservation is recommended.

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG, P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49-62 21/84 44 35, or per e-mail at
kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Sonja Geppert (Organisation Manager) at
+49-62 21/84 44 16, or per e-mail at
geppert@concept-heidelberg.de.